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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,507	11/05/2003	Ali Amara	03495.0301	6288

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
08/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,507	AMARA ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,27-29,31-34,36,40,81,82,91,94-96,98-102,104,105,110 and 111* is/are pending in the application.

4a) Of the above claim(s) *81,82,104 and 105* is/are withdrawn from consideration.

5)☒ Claim(s) *24,27-29,31-34,36,81,82,91,94-96,98-102,104,105,110 and 111* is/are allowed.

6)☒ Claim(s) *40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed May 15, 2007 is acknowledged and entered. Claims 24, 27-29, 31-34, 36, 40, 81, 82, 91, 94-96, 98-102, 104, 105, 110 and 111 are pending. Claims 81, 82, 104 and 105 are withdrawn from consideration, being drawn to non-elected subject matter.

Claims Summary and Interpretation

2. The claims are drawn to a method of treating a CMV infection of a mammal or inhibiting entry of a CMV virus into a cell of a mammal, comprising administering to the mammal a molecule that specifically binds to at least one DC-SIGN receptor. The molecule is administered in an amount sufficient to inhibit the binding of the CMV virus to the DC-SIGN receptor. Specifically, the molecule that binds to the DC-SIGN receptor is a CMV envelope glycoprotein B, or a binding moiety thereof. In another embodiment, the molecule that binds to the DC-SIGN receptor is an antibody, Mab1B10.2.6.

In another embodiment, the claims are drawn to a method of treating an HIV infection or inhibiting entry of an HIV virus into a cell of a human, comprising administering a binding moiety of the CMV envelope glycoprotein B that binds to the DC-SIGN receptor, thus inhibiting the binding of HIV gp120 to the DC-SIGN receptor.

3. The rejection of claims 24, 27-29, 31, 91, 94-96 and 98 under 35 U.S.C. 102(b) as being anticipated by Pass *et al.* (*The Journal of Infectious Diseases*, 1999, 180:970-975, "Pass"), is withdrawn upon further consideration of the claim language and the teachings of Pass. Pass does

not teach or fairly suggest the administration of the vaccine composition to an individual already infected with CMV. The specification defines "treatment" as referring to the administration of therapy to an individual who already manifests at least one symptom of a disease (page 28, paragraph [068]). As pointed out by Applicant, the patient population described in Pass is limited to those that had no detectable serum antibody to CMV. One of the 46 trial participants demonstrated serological evidence of CMV infection after a second immunization with gB in MF59 adjuvant (page 973, second column, second full paragraph). However, this particular patient did not receive a third immunization or subsequent immunization. Therefore, Pass' disclosure does not teach or fairly suggest the administration of gB to a patient already known to be infected with CMV, as required by the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pass *et al.* (*The Journal of Infectious Diseases*, 1999, 180:970-975, "Pass") in view of Cunningham *et al.* (*The New England Journal of Medicine*, 1998, 339(4):236-244, "Cunningham"). The claim is drawn to a method of treating HIV by administering CMV glycoprotein B to an individual. The teachings of Pass are summarized above. Pass does not teach the treatment of HIV. However, it would have been obvious to apply Pass' method to an HIV patient susceptible to or infected with

CMV. One of ordinary skill in the art would have been motivated to treat CMV infection in an HIV patient because CMV is an opportunistic pathogen that routinely infects immuno-suppressed HIV patients, evidenced by Cunningham. Cunningham teaches that CMV retinitis affects 30 to 40% of HIV-positive patients in developed countries whose CD4+ T-cell counts have fallen below 100 cells/mm^3 (page 240, second column). One would have had a reasonable expectation of success that using Pass' CMV treatment would have worked with HIV patients that are susceptible to infection with CMV, given the high prevalence of CMV infection in HIV patients.

Although Pass does not teach that their recombinantly produced CMV gB has the capability to bind to DC-SIGN, the gB is entirely expected to bind DC-SIGN. By administering Pass' gB to humans infected with HIV, DC-SIGN is bound by gB and thus inhibits CMV infection. Further, according to Applicant, CMV gB will also inhibit HIV infection. Therefore, the claimed method is obvious over Pass in view of Cunningham.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that Pass does not describe a method of treating an HIV infection in a patient infected with HIV, but instead teaches a method of immunizing a patient against a CMV infection.

In response to Applicant's arguments, administration of gB to HIV infected individuals inherently treats HIV. As stated previously, it would have been obvious to apply Pass' method to an HIV infected patient susceptible to CMV infection. One of ordinary skill in the art would have been motivated to inhibit CMV infection in an HIV patient because CMV is an opportunistic pathogen that routinely infects immuno-suppressed HIV patients, evidenced by Cunningham. Therefore, the subject matter of claim 40 remains obvious over the prior art.

Conclusion

5. Claims 24, 27-29, 31-34, 36, 81, 82, 91, 94-96, 98-102, 104, 105, 110 and 111 are allowable. Claim 40 remains rejected. It is acknowledged that Applicant requests rejoinder of withdrawn claims. Since not all linking claims are allowable (linking claim 40 is rejected), rejoinder is not appropriate at this point in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 7-3-2007
Primary Examiner, TC1600